



HARMONIZED SYSTEM
COMMITTEE

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31st Session
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O. Eng.

Brussels, 14 March 2003.

CLASSIFICATION OF AN ANTIMYCOTIC AGENT REFERRED TO AS "NATAMAX"

(Item VIII.8 on Agenda)

Reference documents :

36.600E, Annex G/3 (HSC/7 – Report)
41.100E, Annex G/10 (HSC/19 – Report)
NC0631E1 (HSC/30)

NC0655E2, Annex H/17 (HSC/30 – Report)
NS0080E2, Annex A/15 (SSC/18 – Report)

I. BACKGROUND

1. At its 30th Session, the Harmonized System Committee examined the classification of an antimycotic agent referred to as "Natamax".

Antimycotic agent in the form of a powder, containing natamycin (an antibiotic) (approximately 50 %) and lactose (approximately 50 %), used in food manufacture to prevent the growth of moulds and yeasts.

2. One delegate began the discussion of this issue by indicating that the question revolved around the relationship between Note 1 (b) to Chapter 38 and heading 21.06. He referred the Committee to the Explanatory Note to heading 21.06, page 181, item (B), second sentence. In his opinion, the product at issue fit this description, as it was a mixture of a chemical and a foodstuff used to enhance the keeping qualities of foodstuffs. He drew the Committee's attention to the high content of lactose and questioned the role of the lactose in the preparation. In this connection, his administration felt that it was necessary to have more information on this point. As a result, he urged the Committee to ask the Scientific Sub-Committee to provide its views on the role of lactose in the preparation.

3. Another delegate pointed to the description of the product in Doc. NC0631E1, which described the product as an antimycotic agent used in food manufacture to prevent the growth of mould and yeasts. He questioned whether such a product should be classified in heading 21.06. He also drew the attention of the Committee to paragraph 20 of the working document, in which the Secretariat had indicated that "Natamax" extended the useful life of

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food products. Therefore, it could be regarded as being of a kind used for the preservation of foodstuffs. At the same time, as stated in the first paragraph of the Annex to Doc. NC0631E1, "Natamax" had no effect on the appearance, colour or flavour of food products and did not interfere with the nutritional value, taste or odour of food products.

4. He then made reference to the General Explanatory Note to Chapter 38, page 669, second paragraph, which read "The mere presence of "foodstuffs or other substances with nutritive value" in a mixture would not suffice to exclude the mixture from Chapter 38, by application of Note 1 (b)". In his opinion, this Note was directly applicable to the situation at hand. He concluded that although "Natamax" was not identical to "Nisaplin" or to salts for curing or salting mentioned in item (30) of the Explanatory Note to heading 38.24 as regards composition, consistency in the interpretation of Note 1 (b) to Chapter 38 should be maintained. He was, therefore, of the view that the product should be classified in heading 38.24 as proposed by the Secretariat.
5. The Committee finally agreed to send the issue to the Scientific Sub-Committee in order to examine the role of lactose in "Natamax".
6. At its 18th Session, the Scientific Sub-Committee examined the classification of "Natamax" and, in particular, the role of lactose in the product. The observations of the Scientific Sub-Committee are set out below.

II. OBSERVATIONS OF THE SCIENTIFIC SUB-COMMITTEE

7. The Sub-Committee was of the opinion that the role of the lactose in the preparation served multiple purposes :
 - it provided a vehicle for the dispersion of the antimycotic agent;
 - it was used to obtain consistency in the application of the product;
 - it was used as a carrier;
 - it was used as a neutral diluent; and
 - it was used as a standardising agent.
8. When it came to the classification of the product, there was a divergence of views within the Sub-Committee. A majority of delegates felt that after the application of the "Natamax" preparation to the surface of a foodstuff, lactose was present in such small quantities that it would make only a negligible contribution to the nutritive value of the final product. They felt that the quantity of lactose present needed to be reasonably significant in order to add to the nutritive value. In this respect, the mere presence of natamycin on the surface of the product (present at 1 milligram per square decimetre at the upper limit and absent at 5 millimeters from the surface) could not reasonably be said to constitute "use in the preparation of human foodstuff". Consequently, in these delegates' view, the product was not excluded from Chapter 38 by Note 1 (b) to that Chapter. Classification should, therefore, be directed to either heading 38.08 or 38.24.
9. One delegate disagreed with the above conclusion. She agreed with the Secretariat that the lactose in "Natamax" could be regarded as a carrying agent which had been deliberately added to the natamycin. However, in her administration's view, whether a product was used on the surface of a foodstuff or mixed with it should not be a criterion for determining the classification of the product, as had been suggested by the other delegates.

10. Furthermore, she drew the attention of delegates to Note 1 (b) to Chapter 38 and informed the Sub-Committee that Note 1 (b) did not require that foodstuffs or other substances with nutritive value be used for the nutritive value that they contributed to the end product. The Note merely excluded from Chapter 38 those products "... containing foodstuffs or substances of nutritive value". She referred the Sub-Committee to item (30) of the Explanatory Note to heading 38.24 (page 701), for an example of a foodstuff that was excluded from heading 38.24. The small print directed that salts for curing or salting containing added sugar were to be classified in heading 21.06. She argued that the added sugar in the salts may have a function in the end product, but it was certainly not used for its nutritive value. In her administration's view, the "preparation" of foodstuffs would also include the "preservation" of such foodstuffs. In her administration's view, this interpretation was supported by the Explanatory Notes. According to the exclusion in item (30), the same products containing added sugar for the preservation of food were classified in heading 21.06. The added sugar was not used for its nutritive value. On this basis, she concluded that her administration would classify "Natamax" in heading 21.06 and not in heading 38.24, thereby maintaining consistency in the interpretation of Note 1 (b) to Chapter 38.
11. The Scientific Sub-Committee concluded its discussion on this agenda item by agreeing to put forward both views to the Harmonized System Committee, as well as its conclusions concerning the role of lactose in the preparation.

III. SECRETARIAT COMMENTS

12. As concluded by the Scientific Sub-Committee, lactose serves multiple purposes in the product at issue. It was deliberately added to natamycin (an antibiotic) as a carrier, a neutral diluent, a vehicle for the dispersion, or consistent application of the product and as a standardising agent.
13. It is true that although Note 1 (h) to Chapter 29 allows certain products to be diluted to standard strengths, antibiotics are not specifically mentioned in that Note. Thus none of lactose functions in "Natamax" is compatible with Note 1 to Chapter 29 and it should therefore be excluded from that Chapter. Consequently, Chapters 21 and 38 merit consideration for the classification of the product at issue and the main question that remains is whether Note 1 (b) to Chapter 38 is applicable in this particular case.
14. Note 1 (b) to Chapter 38 excludes mixtures of chemicals with foodstuffs or other substances with nutritive value, of a kind used in the preparation of human foodstuffs from Chapter 38 and directs them generally to heading 21.06.
15. According to the Explanatory Note to heading 21.06 (Item (B) on page 181, second sentence) this heading includes preparations consisting of mixtures of chemicals with foodstuffs, for incorporation in food preparations either as ingredients or to improve some of their characteristics (appearance, keeping qualities, etc.). The Explanatory Note further refers to the General Explanatory Note to Chapter 38.
16. As stated in the General Explanatory Note to Chapter 38 (the second paragraph on page 669) the mere presence of foodstuffs or other substances with nutritive value in a mixture would not suffice to exclude the mixture from Chapter 38 by application of Note 1 (b).

17. This Note should be, in the Secretariat view, read and interpreted as a whole and it would apply only when both conditions contained in its wording are fulfilled, i.e., (i) when dealing with mixtures of chemicals with foodstuffs or other substances with nutritive value and (ii) when these mixtures are of a kind used in the preparation of foodstuffs (emphasis added).
18. As recalled by the Secretariat in paragraphs 17 and 18 of Doc. NC0631E1, Note 1 (b) to Chapter 38 was studied by the Committee on several occasions in the past, for example, during the discussions on the classification of "Nisaplin" and on the possible amendment of the Explanatory Note to heading 38.24 concerning salts for curing or salting (see Annex G/3 to Doc. 36.600 (HSC/7 – Report) and Annex G/10 to Doc. 41.100 (HSC/19 – Report), respectively). In the context of the respective decisions taken by the Committee, it appears that the preparation of foodstuffs should be distinguished from the preservation of foodstuffs. Hence, Note 1 (b) to Chapter 38 should not be applicable to mixtures of chemicals with foodstuffs or other substances with nutritive value which are not of a kind used in the preparation of human foodstuffs.
19. "Natamax" is used to extend the useful life of food products, such as cheeses, meats or fruit juices. This effect is achieved by means of inhibition and/or elimination of moulds and yeasts. "Natamax" is generally applied in the final stage of cheese production for the surface treatment of cheese products, by immersion bath or by means of sprayers, to prevent formation of mould. In the production of meats, it is recommended to submerge or to dew the meat in the "Natamax" solution. It is also used in dried sausages and in fruit juices to control yeasts and moulds. It can therefore be applied on the surface of the foodstuff or mixed with the foodstuff, depending on the particular field of application. At the same time, "Natamax" has no effect on the appearance, colour, taste or flavour of food products. Under these circumstances, the question to be considered is whether such particular use of "Natamax" could be regarded as the "preparation of human foodstuffs" within the context of Note 1 (b) to Chapter 38.
20. The Scientific Sub-Committee expressed the view that headings 38.08 and 38.24 merit consideration. Heading 38.24 is a residual heading for chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products) and would apply only if the product at issue is not classifiable in heading 38.08.
21. Heading 38.08 covers insecticides, rodenticides, fungicides, herbicides, anti-sprouting products and plant-growth regulators, disinfectants and similar products, put up in forms or packings for retail sale or as preparations or articles. The Explanatory Note to that heading (first paragraph on page 681) clarifies that products are classified in this heading in the following three cases only :
- (i) when put up in packings for retail sale as disinfectants, insecticides, etc., or in such forms (e.g., in balls, tablets or plates) that there can be no doubt that they will normally be sold by retail;
 - (ii) when they have the character of preparations, whatever the presentation (e. g., as liquids, washes or powders). These preparations consist of suspensions or dispersions of the active product in water or in other liquids, or of other mixtures;
 - (iii) when they are in the form of articles, e.g., sulphur-treated bands, wicks or candles.

22. "Natamax" is a product having antifungal properties (it controls the growth of moulds and yeasts) and inhibiting mycotoxin production. It is a blend consisting of two components, an antibiotic (natamycin) and lactose, and it therefore appears to correspond to the category of preparations listed in (ii) above.
23. It should be noted that the Explanatory Note to heading 38.08 (item (IV) on page 682) describes products which destroy or irreversibly de-activate undesirable bacteria, viruses or other micro-organisms, generally on inanimate objects, as disinfectants. They can be used, *inter alia*, in the manufacture of animal feeds to control undesirable micro-organisms.
24. On the other hand, the Secretariat wishes to reiterate the similarity between "Natamax" and "Nisaplin". "Nisaplin" was classified in heading 38.24 and in Classification Opinion 3824.90/3 it is described as an antibiotic concentrate in the form of a white, micronised powder, containing nisin (an antibiotic), sodium chloride and milk proteins (a residue from the manufacturing process of nisin), used in food manufacture to prevent the growth of bacteria.
25. The Secretariat has already expressed its classification views in Doc. NC0631E1 and it feels that the principal question to be considered is whether "Natamax" could be regarded as being "of a kind used in the preparation of human foodstuffs" within the context of Note 1 (b) to Chapter 38. If the answer is yes, the product at issue would be classifiable in heading 21.06 (subheading 2106.90). If the Committee feels that to be consistent with the decisions taken in the past, the preparation of foodstuffs does not cover the preservation of foodstuffs, the product at issue should not be excluded from Chapter 38. In that case, it would be up to the Committee to decide whether "Natamax" is classifiable in heading 38.08 (subheading 3808.20) or in heading 38.24 (subheading 3824.90).

IV. CONCLUSION

26. The Committee is invited to rule on the classification of the antimycotic agent "Natamax", taking into account the observations of the Scientific Sub-Committee and the comments of the Secretariat above.
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